

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY) MDL NO. 1456
AVERAGE WHOLESALE PRICE)
LITIGATION) CIVIL ACTION: 01-CV-12257-PBS
) Subcategory Docket: 06-11337-PBS
)
THIS DOCUMENT RELATES TO) Judge Patti B. Saris
)
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., No. 07-CV-) Magistrate Judge Marianne B. Bowler
11618-PBS; *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc. et al.*, No. 05-)
11084-PBS; *U.S. ex rel. Ven-a-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corp.*, et al., No. 07-10248-PBS)

**DEFENDANTS' JOINT MEMORANDUM IN SUPPORT OF DEFENDANTS'
MOTION TO COMPEL RELIEF ON OUTSTANDING DELIBERATIVE PROCESS
PRIVILEGE ISSUES AND IN RESPONSE TO THE MEMORANDUM OF THE UNITED
STATES RELATING TO THE *IN CAMERA* SUBMISSION OF DOCUMENTS**

Over the past two months, the parties and the Court have made numerous filings, comments, and rulings concerning the Government’s assertion of the deliberative process privilege to withhold crucial evidence from defendants Abbott Laboratories, Inc., Dey, Inc., and the Roxane Defendants (collectively, “Defendants”). While the Court has resolved some issues, several outstanding matters concerning the deliberative process privilege remain. This memorandum collects those outstanding issues, and supports Defendants’ specific requests for relief. The outstanding issues are as follows:

- 119 documents submitted for *in camera* review still require judicial review. Defendants request that the Court either order production of the documents, or appoint a special master to conduct the review.
- The Government still has not produced or submitted for *in camera* review entrance and exit conference minutes from certain key OIG reports. Defendants ask that the Court order the Government to search its files and produce those missing documents.

- Judge Saris explicitly ruled that communications outside the agency are not protected by the deliberative process privilege. Defendants therefore ask that the Court order production of all communications outside the agency previously withheld on a claim of privilege.
- Given their demonstrated relevance, the Court should also order the Government to produce or submit for *in camera* review all responsive documents from the Office of Legislation and specified Rulemaking Support Files. All documents not produced should be placed on a privilege log.
- The Court should also order production of a final, unredacted version of the CMS “decision memorandum” concerning the criteria used by the Government to approve states’ payment rates to providers for dispensing drugs to Medicaid beneficiaries. *See Abbott’s Motion to Compel Production of Documents from the United States* (Dkt. No. 5173).
- The Court should separately adjudicate, or have a special master separately adjudicate, the obstructed deposition testimony described in Abbott’s Motion to Compel Testimony from Government Witnesses (Dkt. No. 5112).

Adding to this list of unresolved issues, just last week—on the very last day of fact discovery in the Dey and Roxane cases (also the last day of expanded state discovery in the Abbott case)—the Government inexplicably and unexpectedly dumped on Defendants 30 CDs of apparently new material “pertaining to various states, including: Arkansas, Georgia, Kentucky, Louisiana, Massachusetts, Minnesota, Mississippi, Montana, New Jersey, New Mexico, New York, North Carolina, North Dakota, Texas, Virginia, and Washington.” (Ex. A.) The Government’s last-minute production is particularly egregious in light of the fact that Defendants just conducted depositions relating to many of these states. Defendants’ preliminary review of the material suggests that the previously undisclosed documents are important and may provide grounds for reopening certain depositions.

In sum, many matters require judicial resolution before fact discovery can be completed. Defendants respectfully submit that the Court should grant their Motion for Appointment of a Special Master (Dkt. No. 5675) to oversee resolution of these issues.

BACKGROUND

Recent events leave no doubt that the Government has overreached in its assertion of the deliberative process privilege in these cases. Judge Saris has criticized the Government for being too aggressive in withholding documents, including its failure to produce “factual recitations,” “post-policy” documents, “old” documents, or communications “outside the agency.” (See Nov. 13, 2008 Hrg. at 15-18.) Given these underlying concerns—and the need to assess the applicability of the privilege “page by page and paragraph by paragraph”—the Court has agreed with Defendants that appointment of a special “master makes sense.” (*Id.* at 16, 28.)¹

The Court ultimately deferred ruling on Defendants’ request for a special master until the Government decided if it would continue to assert privilege over 184 specific documents listed on Schedule 1 to Defendants’ memorandum in support of their motion for appointment of a special master. (See Nov. 13, 2008 Hrg. at 30.)² The Government has since decided to “release” all or part of about 115 of the 184 Schedule 1 Documents. But the long-delayed production of these documents only raises more questions about the Government’s gamesmanship. Many—if not most—of the recently released documents should never have been withheld in the first place, as they clearly do not meet the “pre-decisional” and “deliberative” prerequisites of the privilege. Examples include the following:

- 1991 memoranda that summarize OIG’s conversations with Red Book, the American Society of Clinical Oncologists, and a drug manufacturer relating

¹ Defendants moved for appointment of a special master after the United States failed to submit a number of documents for *in camera* review, and after Judge Saris’s November 5, 2008 decision revealed serious problems with the Government’s assertion of the privilege. (See Dkt. No. 5676 at 13-19.) Judge Saris has recently referred Defendants’ motion for appointment of a special master, as well as resolution of the Government’s most recent *in camera* submission, to Magistrate Judge Bowler.

² To focus the Court’s review of Defendants’ request for a special master, Defendants asked that the Court conduct, or have a special master conduct, an *in camera* review of 184 particular documents (hereafter, the “Schedule 1 Documents”). Judge Saris ordered the Government at the November 13th hearing to either produce the Schedule 1 Documents to Defendants or submit them for *in camera* review.

to, *inter alia*, sources of pricing information and how AWPs are calculated and reported (HHD966-0061-0069, 0188-0190, 0283-0286, 0287-0288);

- A November 9, 1995 “Draft Memorandum” of a meeting between OIG and a supplier concerning fraud and abuse in Medicare, including the supplier’s statement that Medicare’s “pricing policy encourages fraud in that providers can gain profits by supplying Metaproterenol to their Medicare patients” (HHD917-0001-0003) (a final memorandum was not produced);
- A “Draft Memo w/Attachments” which purportedly “provid[es] background on and transmits HHS report to Congress on the average wholesale price of drugs as mandated by Section 4556 of the Balanced Budget Act of 1997,” but in truth is a cover letter with important factual information about AWP (e.g., “. . . AWP is an unregulated suggested price typically set by the manufacturer that bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace.”) (HHC902-0975-0800) (again, a final memorandum was not produced);
- Notes of a June 13, 1988 meeting between OIG and the Texas Department of Human Services relating to drug pricing and AWP (HHD971-0621-624); and
- Letters dated in February and March of 1995 from a Medicare carrier Medical Director providing HCFA with information about the differences in Red Book pricing and market prices for albuterol and Lupron, advising HCFA “that the ‘Red Book’ and ‘average wholesale price’ are manufactured terms and totally unrelated to drug pricing,” and urging HCFA “to eliminate all references to these terms in published regulations and carrier instructions” to avoid the “extraordinary profit” made by providers (HHD920-2231-2232, HHD919-0022-0024).

These examples are just the beginning. Over half of the recently released documents do not meet the prerequisites of the deliberative process privilege, and nearly all of the documents contain segregable factual information that should have been produced. This, of course, raises the question of what else has been withheld that should have been produced long ago. Of particular concern, many of these withheld documents were never placed on a privilege log.

Counsel for Defendants have attempted to confer with counsel for the Government to resolve this concern and the other outstanding deliberative process privilege issues addressed in this motion. (See Ex. B, Nov. 20, 2008 Ltr. from D. Torborg to J. Draycott; Ex. C, Dec. 5, 2008

Email from D. Torborg to J. Draycott; Ex. D, Dec. 16, 2008 Email from D. Torborg to J. Draycott.) Counsel for the Government has not responded to these inquiries.

ARGUMENT

I. THE COURT SHOULD ORDER IMMEDIATE PRODUCTION OF THE GOVERNMENT'S REMAINING *IN CAMERA* SUBMISSIONS, OR APPOINT A SPECIAL MASTER TO CONDUCT A THOROUGH *IN CAMERA* REVIEW.

The Government has submitted *in camera* 119 documents that still require judicial review. These documents were submitted on December 4, 2007 (Dkt. No. 4920) (21 documents), June 3, 2008 (Dkt. No. 5353) (21 documents), and December 8, 2008 (75 documents). Each of these 119 documents requires an individualized analysis that, as Judge Saris has recognized, should be performed “page by page and paragraph by paragraph.” (Nov. 13 Hrg. at 28.) Given the tremendous strain already placed on this Court by the MDL litigation, appointment of a special master is necessary and appropriate. (*See id.* at 15: “[I]t took me forever to go through the twelve documents because it’s not all or nothing, you know. I mean, when you go through them, some of it’s protected, some of it’s not, some of it I’d have to balance. It takes forever, and I can guarantee you I am not going to sit -- or I just talked to Judge Bowler. She said it would be impossible for her to go through.”).³

Alternatively, it would be perfectly appropriate—and not at all unfair to the Government—for this Court or a special master to order production of each of the 119 documents without an *in camera* review. “[T]he time to make the showing that certain information is privileged is at the time the privilege is asserted, not months later when the matter

³ Courts commonly appoint a special master to review the Government’s assertion of the deliberative process privilege to withhold large volumes of documents. *See, e.g., United States v. Phillip Morris USA Inc.*, 218 F.R.D. 312, 315-317 (D.D.C. 2003) (adopting special master’s finding that Government improperly invoked deliberative process privilege with respect to certain documents); *Cobell v. Norton*, 213 F.R.D. 1, 7-9 (D.D.C. 2003) (directing special master to determine whether documents withheld by Government fell within the deliberative process privilege).

is before the Court on a motion to compel.” *Anderson v. Marion County Sheriff’s Dep’t*, 220 F.R.D. 555, 562 n.5 (S.D. Ind. 2004). Here, the Court permitted the Government to submit affidavits to support its privilege assertions after Abbott filed a motion to compel. As Judge Saris recently commented, however, the Government’s supporting declarations were plainly insufficient. *See* Nov. 13, 2008 Hrg. at 40 (“[Y]ou didn’t give me a declaration that went document by document. . . . [T]hey were broad-sweeping, the end of the Republic if these are produced.”); *Pac. Gas & Elec. Co. v. United States*, 71 Fed. Cl. 205, 209 (2006) (government’s “vague, general and conclusory statement[s] as to why the confidentiality of the listed documents should be maintained” insufficient) (internal quotation marks omitted).

Now, after hearing Judge Saris’s comments, the Government attempts to bolster its privilege assertions with slightly more detailed declarations. But the only real improvement in the new declarations is that they separately describe the withheld material. The declarations still fail to explain “with particularity how or why disclosures of the substance of the documents would harm an identified deliberative function.” *Id.* at 209 (emphasis and internal quotation marks omitted). Instead, they merely parrot, collectively for all of the documents at once, the same general language contained in the Government’s previous declarations. (*See* Dkt. No. 5750, Ex. 1, ¶¶ 7-12, Ex. 2, ¶¶ 16-21.)

The Court would be well within its discretion to decide it will no longer tolerate the Government’s overreaching and, instead, will hold the Government to the consequences of its inadequate assertions of the qualified privilege. *See Mobil Oil Corp. v. Dep’t of Energy*, 102 F.R.D. 1, 7 (N.D.N.Y. 1983) (unless procedural prerequisites are enforced, government agencies are encouraged “automatically to claim the broadest possible grounds for exemption for the greatest amount of information,” “shift[ing] the burden of proving the necessity of such claims

away from the agency and on to the already heavily burdened court system”) (internal quote marks omitted). The Court could simply order that the 119 documents be produced. *See Pac. Gas & Elec. Co. v. United States*, 70 Fed. Cl. 128, 136-37 (Fed. Cl. 2006) (concluding that a balancing test was unnecessary because, “first, [the Government] has failed to demonstrate that the privilege was properly invoked by the appropriate official; second, [the Government] has failed to ‘supply the court with ‘precise and certain reasons’ for maintaining the confidentiality of the requested documents[s],’ . . . and third, [the Government’s] affidavits supporting its assertions of the deliberative process privilege have been belatedly executed.”) (citations omitted).

Finally, even if the Court determines that a balancing analysis is required, the Court or special master should order production of a vast majority of the remaining 119 documents. These documents are of critical importance to Defendants, particularly the notes of the entrance and exit conferences to numerous OIG reports—the importance of which are discussed in detail at pages 16-19 of Defendants’ memorandum in support of the appointment of a special master (Dkt. No. 5676). In short, these minutes will likely shed light on *why* Medicare and Medicaid continued to pay well in excess of acquisition cost despite being told of the “mega-spreads” that providers were receiving. The Government’s discussion on pages 13-14 of its brief (Dkt. No. 5750) fails to explain why this material should not be produced to Defendants. Indeed, the Government fails to explain how discussions *of the findings of an OIG report* are pre-decisional or deliberative at all. There is no explanation of what “decision” is being vetted. The Government instead makes a strained argument that the entrance and exit conferences notes are “conceptually very similar to draft versions of the final report.” (Dkt. No. 5750 at 14.) If that is

all they are (which, frankly, Defendants doubt), then the documents are neither pre-decisional nor deliberative and Government should simply produce them.

Moreover, the Court should order the Government to re-review its files to locate and then submit for *in camera* review the minutes of entrance and exit conferences for certain key OIG reports, namely:

- 1997 reports relating to OIG's audit of the difference between AWP and invoice costs for brand-name and generic drugs;
- OIG's updated audit in 2001-02 of the difference by AWP and invoice costs for brand-name and generic drugs;
- a 1992 OIG report comparing AWP and estimated acquisition cost for dialysis-related drugs (including Vancomycin);
- a 1992 OAS report comparing AWP and estimated acquisition cost for chemotherapy drugs; and
- a 1997 report comparing Medicare reimbursement to catalog prices (including for many of the drugs at issue).

These are among the most important OIG reports to the cases; for whatever reasons, the conference notes for them have been neither produced nor logged. The lead agent for many of these reports, OIG's Ben Jackson, recently testified that there should be minutes of conferences for the 1997 OIG audit work (category 1) in the work-paper files. (*See* Ex. E at 348.) Tellingly, when asked if it would bother him if Defendants could review the notes, Mr. Jackson candidly replied (twice), "No." (*Id.* at 348-49.)

As to the remainder of the 119 documents still at issue, the Government's descriptions offer little insight into their contents. However, Defendants have previously heard the Government claim that withheld documents are "irrelevant to any claim or defense in the case," only to find the exact opposite when documents were eventually produced. Enough is enough.

II. THE COURT SHOULD ORDER IMMEDIATE PRODUCTION OF WITHHELD DOCUMENTS INVOLVING COMMUNICATIONS OUTSIDE THE AGENCY.

Judge Saris has very clearly ruled that communications outside of the agency are not covered by the deliberative process privilege.⁴ Defendants thus asked the Government to “identify and then produce any documents previously withheld that represent communications with individuals outside the agency (such as carrier documents and communications with state employees).” (Ex. B.) The Government has ignored this request.

Instead, the Government apparently seeks to re-argue Judge Saris’s ruling, asserting in its recent brief that the “fact that [a] document was shared with a DMERC medical director does not vitiate the protection afforded by the deliberative process privilege.” (Dkt. No. 5750 at 12.) The Court’s ruling is supported by plain language on the basic scope of the deliberative process privilege,⁵ and the Government has not moved for reconsideration of the ruling. The Government cannot just refuse to produce documents that the Court has found to be outside the scope of protection. The Court should order immediate production.

III. THE COURT SHOULD ORDER PRODUCTION OR *IN CAMERA* SUBMISSION OF ALL RESPONSIVE DOCUMENTS FROM THE OFFICE OF LEGISLATION AND SPECIFIC RULEMAKING SUPPORT FILES.

Judge Saris’s concerns about the overbreadth of the Government’s assertion of the deliberative process privilege are especially pertinent to the Office of Legislation files and the Rulemaking Support Files. Six of the twelve documents included in the Court’s November 5, 2008 opinion were produced from these sources. (See Dkt. No. 5665 at 17-20.) After

⁴ See Dkt. No. 5663 at 20 (“The document was prepared by a medical director employed by a carrier (Cigna), not CMS. It is not privileged because it does not reflect an internal agency deliberation.”); Nov. 13, 2008 Hrg. at 16 (“there were ones that were from outside the agency, I forget, some carrier. They weren’t even protected.”); 18 (“So any carrier documents shouldn’t be [withheld].”)).

⁵ See *Madison County v. United States Dep’t of Justice*, 641 F.2d 1036, 1043 (1st Cir. 1981) (noting the deliberative process privilege covers “only (1) intra- or inter-agency communications (2) that are not available to a private party in litigation with the agency”).

conducting an individualized review of these six documents, the Court found that five should be produced in whole or redacted, either because the documents were not privileged at all or because Defendants' need for the documents outweighed the Government's interest. (*See id.*)

As the Court may recall, the Government has deemed all documents from the Office of Legislation and the Rulemaking Support Files to be covered the deliberative process privilege. Magistrate Judge Bowler denied Abbott's motion to compel production or a privilege log from these sources. (*See* Electronic Order dated 2/1/08.) However, Magistrate Judge Bowler's finding that the "burden imposed outweighs the likely benefit of the information" (*id.*) was not based on the review of any of the disputed documents. (*See* Nov. 5, 2008 Op., Dkt. No. 5665 at 9-10: "In conducting a balancing test, a court should conduct an individualized review of each piece of evidence to 'to insure that the balance between petitioners' claims of irrelevance and privilege and [the opposing party's] need for documents is correctly struck.'") (citing *Kerr v. U.S. Dist. Ct. for N. Dist. of Cal.*, 426 U.S. 394, 405 (1976)).⁶

The fact that Judge Saris ordered five out of the six documents from the Office of Legislation and Rulemaking Support Files be produced, coupled with the demonstrated overbreadth of the Government's withholdings, compels Defendants to (respectfully) revisit this issue. There can be no dispute that these documents are a fertile source of relevant information that has not yet been produced to Defendants. There is nothing cumulative about these documents. The Court should order the Government to produce or submit for *in camera* review all responsive documents from the Office of Legislation and Rulemaking Support Files. Under these circumstances, Defendants respectfully submit that allowing the Government to suppress

⁶ The 184 documents listed on Schedule 1 to Defendants' special master briefing do not include any documents from its Office of Legislation or Rulemaking Support Files. This is because the Government did not separately log them.

these documents—with no privilege log and no opportunity for review by a neutral party—would constitute reversible error.⁷

In considering this request of the Office of Legislation files, the Court should appreciate the importance of these documents to the upcoming depositions of former CMS employees Ira Burney and Debbie Chang. (Magistrate Judge Bowler denied the Government's motion to quash these depositions during the December 4, 2008 motions hearing.) Mr. Burney and Ms. Chang worked in the Office of Legislation during the 1990s on drug policy issues. Without timely production of documents from the Office of Legislation, the depositions of Mr. Burney and Ms. Chang will be unnecessarily delayed. Worse, Defendants may be forced to depose these witnesses without the documents, only to seek another round of depositions after production.

IV. THE COURT SHOULD ORDER PRODUCTION OF THE CMS DECISION MEMORANDUM.

Abbott has previously moved to compel production of an “unredacted, final version of a ‘decision memorandum’ concerning the Government’s approval of the way in which state Medicaid programs paid providers and dispensed drugs to Medicaid beneficiaries, which the Government has already produced in draft form.” (Dkt. No. 5173.) Magistrate Judge Bowler heard argument on this issue during the December 4, 2008 motions hearing, but deferred her ruling when Government counsel indicated it would “probably revisit the redactions and see if there were some parts of it that might be unredacted.” (Dec. 4, 2008 Hrg. at 49.) It has been over two weeks since the hearing, and the Government has yet to act on its promise.

⁷ In addition, as noted in Defendants’ memorandum in support of their motion for appointment of a special master, there is no indication that the Government has complied with the Court’s directive at the July 24, 2008 hearing to re-review the relevant Rulemaking Support Files. (See Dkt. No. 5676 at 17-18.) The Government should be directed to review the Rulemaking Support Files for each of the regulations listed in previous discovery requests, as well as the reasonably small list of additional regulations listed in pages 18-19 of Defendants’ memorandum.

In multiple briefs and even at oral argument, the Government has failed to provide any legitimate reason why it has not produced this document. As Magistrate Judge Bowler stated during the hearing, because the Government has already produced a draft version of the document, the “cat is out of the bag.” (*Id.* at 48.) Moreover, given the importance of this document—the extent of testimony directed to the draft is proof enough of that—any balancing test that might be required clearly tips in Defendants’ favor. The Government has failed to enunciate any particularized harm that would result from disclosure of this particular document. The Court should order a complete unredacted copy of the document immediately.

V. THE COURT SHOULD OVERRULE THE GOVERNMENT’S INSTRUCTIONS TO FEDERAL WITNESS NOT TO ANSWER DEPOSITION QUESTIONS.

The Court also heard oral argument on Abbott’s Motion to Compel Testimony of Government Witnesses (Dkt. No. 5112) during the December 4, 2008 motions hearing. The Court took this motion under advisement, and later directed the parties to “further consult and discuss each objected to question with respect to each deposition in the context of Judge Saris’ recent deliberative process rulings and any related rulings on appeal of my rulings.” (Dec. 4, 2008 Hrg. at 25, 61.) Because the Government has ignored Abbott’s request to confer on these issues, Abbott is renewing the motion.

The Government frivolously argues that the Court has already “decided” this motion. As explained in detail in Abbott’s reply brief on this motion (Dkt. No. 5151, Ex. A), neither Magistrate Judge Bowler nor Judge Saris has even remotely decided the issues posed by this motion. The Government cannot point to any decision from either the Magistrate or District Court that resolves or even addresses the particular testimony put at issue in Abbott’s motion.⁸

⁸ The Government has made the curious argument that Judge Saris’s ruling about draft OIG reports somehow translates to a ruling concerning discovery into the important entrance and exit conferences. (Dec. 4, 2008

The fact that Abbott discussed some of the blocked testimony in prior filings to illustrate the overbreadth and fundamental unfairness of the Government's conduct in these cases does not mean that the Court adjudicated those issues raised by Government counsels' instructions.

The Court's decision to defer consideration of the propriety of the Government's privilege objections during depositions is consistent with the well-established principle that privilege issues should be decided on a question-by-question basis once the deposition has taken place, the privilege has been asserted, and a proper record has been created and presented to the Court for review. *See United States v. Lawless*, 709 F.2d 485, 487 (7th Cir. 1983) ("The claim of privilege must be made and sustained on a question-by-question or document-by-document basis: a blanket claim of privilege is unacceptable."); *Evans v. City of Chicago*, 231 F.R.D. 302, 320 (N.D. Ill. 2005) ("the proponent of the privilege must establish the privilege on a document-by-document (or question-by-question) basis").

The Government's faulty reliance on the Court's general pronouncements regarding the discoverability of *documents* is contrary to this law and the Court's past practice of examining privilege assertions in the context of depositions. (*See* Dec. 18, 2006 Hrg. at 136 (Saris, J.) (Ex. F) (rejecting the plaintiffs' request for "broad rulings" that the witness's testimony was not privileged, and instead indicating that a "question-by-question" analysis is preferred).) This Court has yet to decide whether the Government's suppression of testimony in the specific questioning put at issue by Abbott's motion—for any of the witnesses—was proper. The Court should separately adjudicate, or request that a special master separately adjudicate, each of the

(continued...)

Hrg. at 16.) Defendants expect that a Court or special master's *in camera* review of the entrance and exit conference minutes will demonstrate the absurdity of this argument.

questions put at issue by Abbott's motion. The testimony is vitally important, and the Government should receive no benefit from its obstructionist behavior.

CONCLUSION

For the foregoing reasons, Defendants respectfully submit that the Court should order the relief requested herein.

Dated: December 31, 2008

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CERTIFICATE OF SERVICE

I, Brian J. Murray an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 31st day of December 2008.

/s/ Brian J. Murray